K030708

Bio-Medical Research Ltd
Parkmore Business Park, West
Galway
Ireland

JUN 25 2003

510 (k) Summary of Safety and Effectiveness.

This summary is submitted in accordance with 21 CFR 807.92

a)	1	Submitted by	Bio-Medical Research Ltd BMR House Parkmore Business Park, West Galway Republic of Ireland
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		Title	Regulatory Affairs Manager
		Date of Preparation	February 2003.
	2	Trade Name of Device system. Type 515.	Slendertone FLEX Abdominal Training
		Common Name	Muscle Stimulator
		Classification name	Powered Muscle Stimulator
	3	Identification of predicate device	Slendertone FLEX Abdominal training system. K010335

4 Description of Device

The Slendertone Flex Abdominal Training system is a two- channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It comprises two main components, namely, an electronic stimulator module which generates the required stimulation signals, and an abdominal electrode belt, which connects the signals from the stimulator to the skin electrodes located on the inner surface of the belt. In effect, the belt in this case takes the place of the lead-wires in most conventional muscle stimulators.

The product is supplied with a set of double- sided adhesive electrodes, an instruction manual, a set of batteries, and a carry pouch. Power is derived from three AAA cells located in a compartment protected by a removable battery cover.

Although a two- channel system, there are only three electrodes, since the central umbilical electrode is common to the each of the left and right stimulation circuits. The electrodes connect adhesively to studs on the inner surface of the belt. The user extends the belt and puts it on in a wrapping motion from front to back, closing it at the back using the hook and loop patches. When the belt is in place on the body the larger center electrode locates over the umbilicus and the two side electrodes locate on either side of the body towards the mid axillary line, between the pelvis and the ribcage. It has been found that this electrode positioning is particularly useful for stimulating the abdominal muscles.

The pulsed stimulation current passes between the side and center electrodes only. There is no current passed from side to side. Because the user has no access to the wiring or connectors within the belt, he/she cannot alter the current path and so the possibilities for mis-use are greatly reduced

5 Intended Use

The Slendertone Flex device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes for the purpose of improving abdominal muscle tone.

The device is indicated for the improvement of abdominal muscle tone, for strengthening of the abdominal muscles and for developing a firmer abdomen.

6 Technological Comparison

The Slendertone Flex device is similar to the original Slendertone FLEX abdominal training system , type 512 and delivers a stimulation signal which is identical .The device is restricted in its range of available stimulation parameters and is restricted in terms of electrode positioning , since the electrodes are integrated in the belt.

7 Technological Comparison

The two Slendertone FLEX Abdominal training systems are the same in delivery of the stimulation signal and have similar parameter settings. There are similar restrictions between the two devices in that electrode positioning is governed by and integral to the garment. Both products utilise a LCD screen with user compliance logging.

Non clinical Tests

Comparisons of electrical outputs for the two devices show similar results. They have both been designed and independently tested to the following requirements;

- IEC 60601-1:1990 Medical electrical equipment – Part 1: General requirements for safety.
- IEC 60601-2-10
- IEC 601-1-1 and appendices A1:1991,A2:1995
  IEC 601-1-2: EMC requirements
- IEC 61000-4-2:1995: Electromagnetic compatibility
- IEC 61000-4-3:1997: Electromagnetic compatibility
- DD ENV 50204:1996: Electromagnetic compatibility
- EN 55011:1998: radiated emissions.

Bio-Medical Research Ltd, (BMR), adheres to recognised and established industry practice, and all devices are subject to final performance testing.

A hazard analysis, a risk analysis and a failure mode effects analysis have been carried out for the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

Helen Gallagher
Regulatory Affairs
Bio-Medical Research Limited
BMR House
Parkmore Business Park, West
Galway
Republic of Ireland

Re: K030708
Trade/Device Name: FLEX, Type 515
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 20, 2003
Received: June 2, 2003

Dear Ms. Gallagher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):	Not known
Device Name:	Slendertone Flex Abdominal Training system, type 515.
Sponsor Name:	Bio-Medical Research Ltd.

The device is intended for over the counter sale.

Indications for Use:

The improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030708